IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to:	:	CIVIL ACTION NOs.:
Pauline Rickard	:	1:21-cv-03861-LMM [140]
Melody Braxton	:	1:22-cv-00490-LMM [98]
Alisa Robere	:	1:22-cv-01583-LMM [111]

ORDER

This case is part of a multi-district litigation ("MDL") involving the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The case is now before the Court on Teva's Motion to Certify Order for Interlocutory Appeal Pursuant to 28 U.S.C. § 1292(b).[1] Upon due consideration, the Court enters the following Order.

I. LEGAL STANDARD

A district court may certify an order for interlocutory appeal if it finds that the following three elements are met: (1) the subject order "involves a controlling

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc.

question of law"; (2) there is a "substantial ground for difference of opinion" on the controlling question of law; and (3) an immediate appeal from the subject order "may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b).

The question of whether an interlocutory appeal would materially advance the ultimate termination of the litigation is often tied closely to consideration of whether the question of law is "controlling," rather than a piecemeal or side issue. Consumer Fin. Prot. Bureau v. Frederick J. Hanna & Assocs., P.C., 165 F. Supp. 3d 1330, 1334 (N.D. Ga. 2015) (citing Ga. State Conference of the NAACP v. Fayette Cnty. Bd. of Comm'rs, 952 F. Supp. 2d 1360, 1362 (N.D. Ga. 2013) (hereinafter, "Ga. NAACP")). "A question of law is considered 'controlling' if it has the potential of substantially accelerating disposition of the litigation, even if it would not terminate the case." Ga. NAACP, 952 F. Supp. 2d at 1362 (cleaned up). A question is considered a sufficiently pure "question of law" if it is "stated at a high enough level of abstraction to lift the question out of the details of the evidence or facts of a particular case and give it general relevance to other cases in the same area of law." McFarlin v. Conseco Servs., LLC, 381 F.3d 1251, 1259 (11th Cir. 2004). In other words, questions of "pure" law are those that "the court of appeals can decide quickly and cleanly without having to study the record." Id. at 1258 (cleaned up).

"[T]he requirement that there be substantial ground for difference of opinion is satisfied when (1) the issue is difficult and of first impression, (2) a difference of opinion as to the issue exists within the controlling circuit, or (3) the circuits are split on the issue." Ga. NAACP, 952 F. Supp. 2d at 1362. Be that as it may, the fact that the issue is one of first impression is not sufficient on its own. Id. "Instead, the district court has a duty to analyze the strength of the arguments in opposition to the challenged ruling when deciding whether the issue for appeal is truly one on which there is a substantial ground for dispute." Id. (cleaned up). A party's strong disagreement with the Court's ruling is not sufficient for there to be a substantial ground for difference of opinion. Consumer Fin. Prot. Bureau, 165 F. Supp. 3d at 1339.

"Certification for immediate appeal of a non-final order under § 1292(b) is an extraordinary measure, which is permitted only in exceptional circumstances." S. Pilot Ins. Co. v. CECS, Inc., 15 F. Supp. 3d 1335, 1336 (N.D. Ga. 2013) (citing McFarlin, 381 F.3d at 1256); accord Caterpillar, Inc. v. Lewis, 519 U.S. 61, 74 (1996) (recognizing that interlocutory appeals are intended for "exceptional" cases). "The proper division of labor between the district courts and the court of appeals and the efficiency of judicial resolution of cases are protected by the final judgment rule, and are threatened by too expansive use of the § 1292(b) exception to it." McFarlin, 381 F.3d at 1259.

II. DISCUSSION

In a prior motion, Teva asked this Court to grant summary judgment in its favor on failure-to-warn and design defect claims brought by bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs"), arguing that those claims are preempted by federal law. Dkt. No. [42].[2] The Court denied Teva's motion on grounds that Plaintiffs presented evidence of "newly acquired information" that would have permitted Teva to correct the allegedly deficient product label by using the Changes Being Effected ("CBE") regulation, which allows for labeling changes without prior FDA approval. Dkt. No. [137] at 9-13. The newly acquired information the Court examined includes a 2015 analysis conducted by Teva Head of Pharmacovigilance, Dr. Siyu Liu, identifying numerous adverse events that had a reasonably strong causal association with the Paragard IUDs at issue in this case. Id. at 9-10.

The Court concluded, over Teva's contrary position, that Dr. Liu's analysis triggered the CBE exception even though it was submitted to the FDA after Plaintiffs' IUD placements. Id. at 10-11. The Court based its decision on evidence that Teva caused the delay in discovering the adverse events by miscoding them and by failing to conduct an FDA-mandated study that would have revealed the adverse events earlier. Id. Based on that evidence, the Court permitted the report

[2] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharmaceuticals USA, Inc., No. 1:21-cv-03861-LMM (N.D. Ga.).

to be used retroactively to establish newly acquired information because the information should have been acquired by Teva earlier. Id. at 10-12. With the CBE exception available, Teva could have complied with both state tort law and FDA requirements, thereby defeating its preemption defense. Id. at 13.

Teva disagrees with the Court's decision that the 2015 report applied retroactively to trigger the CBE exception. Dkt. No. [140] at 1-2. It now asks the Court to stay the bellwether trials—the first of which is set to begin next week—and certify the following question to the Eleventh Circuit for interlocutory review:

> Whether information can retroactively qualify as "newly acquired" under the CBE exception where the information was not actually "acquired" by the drug manufacturing defendant before the relevant time period (i.e., before a plaintiff's ingestion or insertion of the prescription drug).

Id. at 5. The Court declines Teva's request because, while the question presents substantial grounds for a difference of opinion (the second § 1292(b) factor), it is not purely a question of law (first factor) and certifying it for interlocutory review at this stage would not materially advance the ultimate termination of this case (third factor).

Teva's strongest argument for interlocutory review is that the issue here creates substantial grounds for a difference of opinion. See id. at 7-12; Dkt. No. [164] at 4-8. It is beyond dispute that this question, like many involving federal preemption, is a "difficult" one that the Eleventh Circuit has yet to address. Ga. NAACP, 952 F. Supp. 2d at 1362. And courts outside the Eleventh

Circuit that have wrestled with the question have reached diverging conclusions. Compare In re Taxotere (Docetaxel) Products Liab. Litig., 508 F. Supp. 3d 71, 84 (E.D. La. 2020) (holding that the preemption defense failed where newly acquired information permitting a CBE change was presented after the plaintiff began taking the drug but was discoverable, and ignored by the defendant, years earlier), with Gayle v. Pfizer Inc., 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020) (rejecting argument that defendant's failure to analyze preexisting adverse event reports constituted newly acquired information permitting a CBE change), aff'd, 847 F. App'x 79 (2d Cir. 2021). But a party's disagreement with the district court on a difficult or unresolved legal question does not entitle that party to an immediate appeal. See Consumer Fin. Prot. Bureau, 165 F. Supp. 3d at 1339. That is especially true where, as here, the question relies heavily on factual analysis and its resolution would not materially advance the termination of the case.

Despite Teva's attempts to characterize the issue as a "purely legal" one, Dkt. No. [140] at 6, the question of whether information that should have been acquired can apply retroactively to trigger a CBE exception involves fact-intensive analysis that is "especially ill-suited for interlocutory review." In re Equifax Inc. Sec. Litig., No. 1:17-CV-3463-TWT, 2019 WL 3449673, at *1 (N.D. Ga. July 29, 2019). The Court's decision to rely on the analysis that Dr. Liu submitted to the FDA after Plaintiffs' IUDs were implanted was shaped by specific facts in the record:

> that Defendants obscured the breakage reports by miscoding them; that the FDA had ordered a new study of the adverse event reporting to be undertaken years earlier, well before Plaintiffs had their Paragards placed; that Defendants simply failed to do it; and that once Teva did undertake the required analysis, both the breakage risk and the causal relationship became immediately apparent.

Dkt. No. [137] at 11. This type of fact-driven analysis is required for evaluating the sufficiency of newly acquired information and whether that information permitted a defendant to unilaterally change its label without prior FDA approval. See Lyons v. Boehringer Ingelheim Pharms., Inc., 491 F. Supp. 3d 1350, 1363 (N.D. Ga. 2020) (outlining the evidentiary standard of the preemption defense and describing the "newly acquired information" and "FDA action" questions as *factual* questions for the court to decide). It is not the type of determination that can be made apart from the record, unlike the purely legal ones appropriate for interlocutory review. See McFarlin, 381 F.3d at 1258 ("[A]n abstract legal issue or what might be called one of 'pure' law . . . can [be] decide[d] quickly and cleanly without having to study the record." (cleaned up)).

If the Eleventh Circuit were to accept Teva's appeal, which is no guarantee, it would be forced to comb through significant parts of the summary judgment record to provide a well-reasoned answer to the question here. Teva seems to acknowledge that reality, at least to some degree, by citing several out-of-circuit district decisions for the proposition that "courts regularly certify questions of preemption for interlocutory appeal—even when they involve underlying facts." Dkt. No. [164] at 8 (citing In re Taxotere (Docetaxel) Prods. Liab. Litig., 2022 WL

16923721, at *1 (E.D. La. Nov. 14, 2022); Knipe v. SmithKline Beecham, 583 F. Supp. 2d 553, 579-84, 599 (E.D. Pa. 2008); Mendoza v. Procter & Gamble Co., 2024 WL 6874473, at *5 (C.D. Cal. Sept. 30, 2024)). These decisions well illustrate the factually intensive nature of the question that Teva insists is purely legal. For example, in answering the preemption question certified by the Taxotere court, the Fifth Circuit analyzed numerous studies, letters, abstracts, and other pieces of scientific literature to conclude that the defendants did not possess newly acquired information. See Hickey v. Hospira, Inc., 102 F.4th 748, 757-59 (5th Cir. 2024), vacating & remanding, In re Taxotere (Docetaxel) Products Liab. Litig., No. 16-17583, 2022 WL 3042639 (E.D. La. Aug. 2, 2022).

But in this Circuit, certified questions must be abstract enough "to lift the question out of the details of the evidence or facts of a particular case and give it general relevance to other cases in the same area of law." McFarlin, 381 F.3d at 1259. By arguing that the question "whether newly acquired information can be applied retroactively" is purely legal, Teva presumes that the Eleventh Circuit will isolate the question from the evidentiary record to answer it. The Court is not convinced that this can be done. Accordingly, Teva has failed to show that the certified question involves a controlling question of law.

The Court is also not convinced that an interlocutory appeal would materially advance the termination of this MDL or the three bellwether cases. "An interlocutory appeal will materially advance the termination of the litigation

if it promises to advance the time for trial or shorten the time required for trial." Doe ex rel. M.W. v. DeKalb Cnty. Sch. Dist., 1:15-CV-03276-RWS, 2019 WL 13292975, at *2 (N.D. Ga. Jan. 17, 2019) (cleaned up). Discovery has concluded, and the first bellwether case is ready for trial, which is to start next week. Id. Certifying the question for interlocutory appeal, should the Eleventh Circuit even accept it, means staying this bellwether trial, waiting months for the case to be briefed, heard, and decided, reevaluating the case in the instance of a remand, and rescheduling the trials for a far later date.

Moreover, while the preemption issue is a critical one, plenty of other issues important to the ultimate outcome of the bellwether cases and this MDL persist. Teva itself acknowledges some of those issues and says that it will ask the Eleventh Circuit to review the Court's entire summary judgment ruling—including factually dense issues related to the design defect claims that Teva argues the Court wrongly decided—if granted interlocutory review. Dkt. No. [140] at 17 n.5. The Court sees no reason why these issues cannot be raised on appeal after the first bellwether trial, with the benefit of a cleaner and more organized record for the Eleventh Circuit to review. The Eleventh Circuit will also be able to review the numerous other rulings materially impacting the trial.

Accordingly, rather than embarking on a lengthy and piecemealed appellate process, the Court finds it more prudent and efficient to move forward with the first bellwether trial, after which Teva or Plaintiff can appeal. Following

the first bellwether trial (Rickard), the Court will reevaluate whether to delay the second and third bellwether trials to provide the parties with the opportunity to appeal before proceeding further with this case. The Court will hear from the parties on this issue once the first bellwether trial concludes.

III. CONCLUSION

For the reasons above, Teva's Motion to Certify Order for Interlocutory Appeal is **DENIED**. The first bellwether trial, Rickard v. Teva Pharmaceuticals USA, Inc., No. 1:21-cv-03861-LMM (N.D. Ga.), will proceed as scheduled.

IT IS SO ORDERED this 12th day of January, 2026.

Leigh Martin May
Chief United States District Judge